East London NHS
NHS Foundation Trust

FOCUS GROUPS AND INTERVIEWS TO REFINE A STRUCTURED INTERVENTION FOR EXPANDING SOCIAL NETWORKS IN PSYCHOSIS

Short study title: SCENE (WP2)

This protocol has regard for the HRA guidance

RESEARCH REFERENCE NUMBERS

IRAS Number: 229142

TRIAL REGISTRY NUMBER AND DATE

PROTOCOL VERSION NUMBER AND DATE Version: 1.1 Date: 08/06/17

OTHER RESEARCH REFERENCE NUMBERS

SPONSOR

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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Signature:

Date:
08/06/2017

.....

Name: (please print):

Stefan Priebe.....

KEY STUDY CONTACTS

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Committees	Programme Management Group (co-applicants), Lived Experience Advisory Group

STUDY SUMMARY

Study Title	Focus groups and interviews to refine a structured intervention for expanding social networks in psychosis
Internal ref. no. (or short title)	SCENE (WP2)
Study Design	Qualitative focus groups and interviews
Study Participants	Patients with a diagnosis of a psychotic disorder as defined by International Classification of Disease-10 (ICD10) codes F20-29; aged 18-65; receiving secondary care mental health services; capacity to provide informed consent; ability to communicate in English Mental health professionals: aged 18-65; with experience of providing mental health care; employed by participating NHS Trusts; capacity to provide informed consent; ability to communicate in English Carers: aged over 18; informal carer of a family member or friend with a psychotic disorder (ICD-10; F20-29); capacity to provide informed consent; ability to communicate in English
Planned Sample Size	For focus groups: 6-8 clinicians per group (total: 18-24 across 3 groups), 6-8 patients per group (total: 18-24 across 3 groups), 6-8 carers per group (total: 18-24 across 3 groups). For individual interviews: 9 patients
Study duration	11 months and 17 days
Planned Study Period	15th June 2017- 31st May 2018
Study aims and objectives	Aim: To understand views and opinions of patients, carers and mental health professionals of a structured intervention for expanding social networks in psychosis to aid its refinement for further testing. The specific objectives are to: 1. Refine and adapt to the NHS the structured intervention, based on a previous study conducted outside of the United Kingdom, and develop an intervention manual and a training module through focus groups and individual interviews with clinicians and service users. 2. Prepare the most appropriate form of presenting the trial information to facilitate recruitment for future testing.

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this trial)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
National Institute for Health Research	Programme Grant for Applied Research
East London NHS Foundation Trust (supported by Noclor)	Study sponsorship
East London NHS Foundation Trust	NHS treatment and support costs. Permission to conduct study on Trust premises with Trust employees and service users
Tees, Esk & Wear Valleys NHS Foundation Trust	NHS treatment and support costs. Permission to conduct study on Trust premises with Trust employees and service users
Devon Partnership NHS Trust	NHS treatment and support costs. Permission to conduct study on Trust premises with Trust employees and service users
Queen Mary University of London	Substantive employer of Chief Investigator

ROLE OF STUDY SPONSOR AND FUNDER

East London NHS Foundation Trust the sponsor, Noclor Research Support Service is acting on behalf of East London NHS Foundation Trust to assume overall responsibility for the initiation and management of the study. The National Institute of Health Research has provided funding for the study.

ROLES AND RESPONSIBILITIES OF TRIAL MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Study Management Committees

The main roles and responsibilities of each committee are outlined below:

- Programme Management Group

  The Programme Management Group (TMG) includes the PI, 10 co-applicants, the main researchers and patient representatives from the Lived Experience Advisory Panel. The PMG will meet regularly to ensure all practical details of the trial are progressing well and working well and everyone within the trial understands them. The PMG will meet every two to three months initially, and at least three times per year throughout. The project timeline and milestones will be scrutinised at each meeting. More regular and individual meetings between the PIs, the co-applicants and the different parts of the research team will be arranged, including Skype video and teleconferencing, as appropriate.

- Lived Experience Advisory Panel

  The Lived Experience Advisory Panel (LEAP) will be made up of eight individuals with lived experience of either psychosis-related diagnoses and/or experience of caring for someone with a psychosis-related diagnosis. The LEAP will be chaired by the service user co-applicant (Ms Geraldine Allen) whose experience includes working as a Peer Support Worker and trainer as part of ELFT and working as a Service User Researcher on a project run with East London Trust based on recovery. The panel will be recruited from an existing service user and carer group (Service User Group Advising on Research (SUGAR)) and the associated network of users with research interest and experience. The LEAP will meet approximately every 4 months, and meetings will be flexibly arranged, with individuals given the option of either a full or half day meeting. Their role will be specified and the terms of reference agreed during the first meeting. The focus of the LEAP meetings will be to discuss developing the study material (e.g. topic guides for WP2&3); the findings of each work package; and dissemination, including developing plain English summaries so the results are accessible to individuals within services.

Protocol contributors

Dr Domenico Giacco, Catherine Fung, Professor Stefan Priebe

KEY WORDS: Social networks, psychosis, schizophrenia, focus groups, qualitative interviews.

LIST of CONTENTS

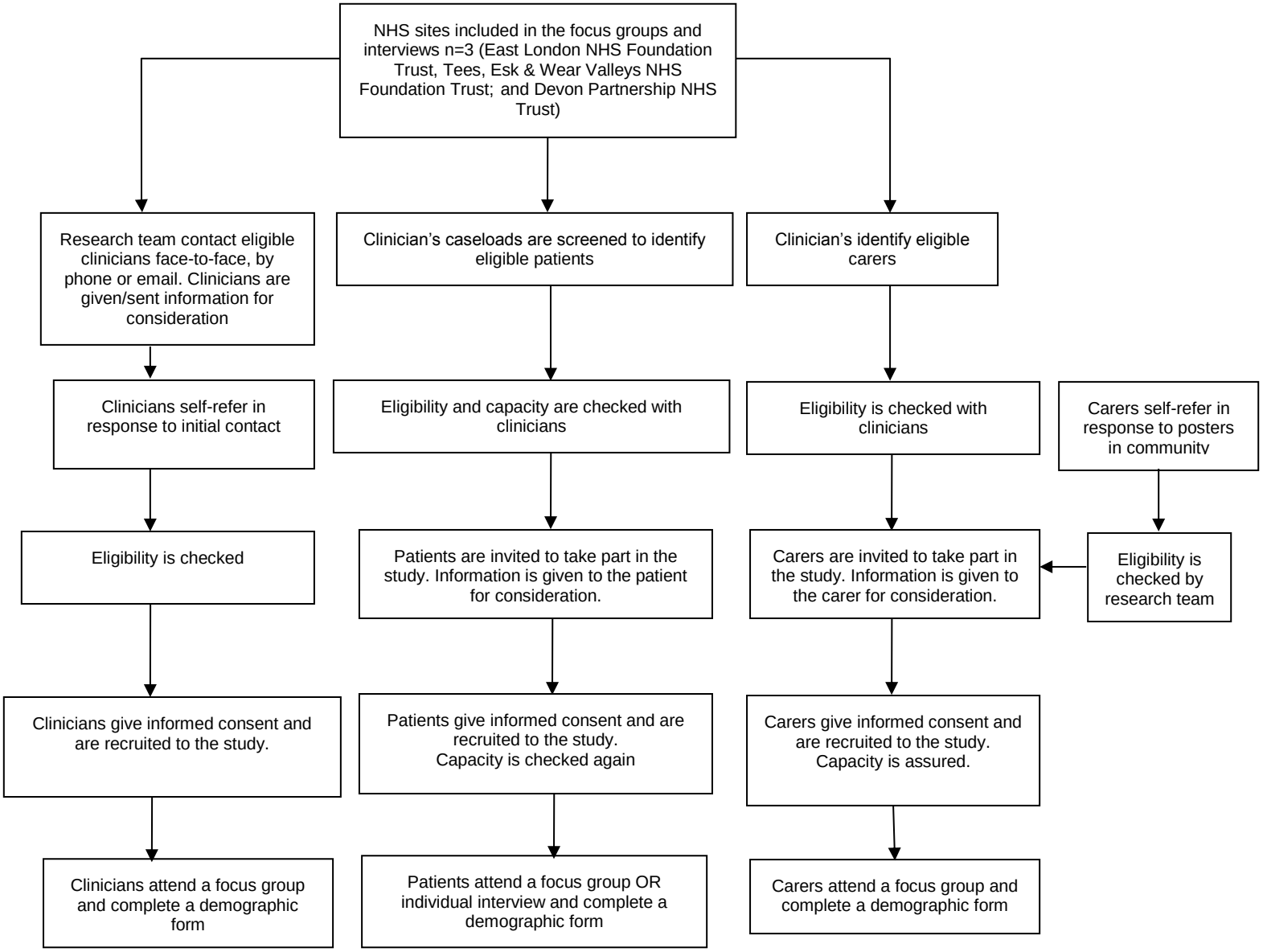
LIST OF ABBREVIATIONS

Define all unusual or 'technical' terms related to the trial. Add or delete as appropriate to your trial. Maintain alphabetical order for ease of reference.

AE	Adverse Event
CA	Competent Authority
CI	Chief Investigator
CRF	Case Report Form
DMC	Data Monitoring Committee
DSUR	Development Safety Update Report
GCP	Good Clinical Practice
ICF	Informed Consent Form
ICD	International Classification of Disease
IDMC	Independent Data Monitoring Committee
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trials Number
NHS R&D	National Health Service Research & Development
NIMP	Non-Investigational Medicinal Product
PI	Principal Investigator
PIC	Participant Identification Centre
PIS	Participant Information Sheet
PMG	Programme Management Group
QP	Qualified Person
RCT	Randomised Control Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SDV	Source Data Verification
SOP	Standard Operating Procedure
SSI	Site Specific Information

STUDY FLOW CHART

Please see Appendix 1 for schedule of events.



STUDY PROTOCOL

Focus groups and interviews to refine a structured intervention for expanding social networks in psychosis

1 BACKGROUND

About 120,000 people with psychosis are being cared for in secondary services in the NHS at any point in time. Reviews show that people with psychosis have much smaller social networks compared with the general population and other groups with long-term mental and physical disorders; and more than 50% of their reduced social networks consist of family members rather than friends and other contacts (Emlet 2006; Palumbo et al. 2015). National Institute for Health and Care Excellence (NICE) (2014) state that one of the symptoms of psychosis is the impairment of the individual's ability to '…maintain relationships; they may become increasingly isolated' (NICE 2014, p.14), therefore isolation for people with psychosis may not always be a choice but a symptom of the illness. Moreover, social isolation is cited as one of the factors related to 'recurrent episodes or relapses' (Nice 2014, p.15).

Recent studies have provided a clear picture of social networks of people with psychosis. In an analysis of data of 1396 patients with psychosis from four international multi-centre studies (Giacco et al., 2012), 45% were found not to have met any friend in the previous week. In a recent survey in East London (Giacco et al., 2016), 80% of patients with psychosis felt lonely, and 43% very or extremely lonely. Only 30% had had more than one social contact in the previous week. Furthermore, research has shown that smaller networks with loneliness, the absence of reliable social contacts and lower social support predict poorer quality of life and unfavourable health outcomes in patients with psychosis (Cohen et al, 1998; Clinton et al, 1998; Bengsson-Tops and Hansson, 2001; Norman et al., 2005). NICE recommendation for care provision states that one of the initial assessments of those presenting to secondary care with psychosis *should* be an 'evaluation of their social networks, relationships' (NICE 2014, p.465).

However, social disadvantages of people with psychosis, such as lack of social activities and social support remain unaddressed in the context of the NHS care provision. A study carried out in Italy has showed that social networks can be expanded with a relatively simple intervention in which mental health professionals help patients to identify their preferences for social activities (Terzian et al., 2013). The overall aim of this NIHR-funded research programme of which this study is a part of, is to adapt this intervention to the NHS and to test whether it expands social networks and improves patients' quality of life.

In this specific study we will aim to understand the views and opinions of patients, carers and mental health professionals regarding a structured intervention to expand social networks. The data collected will aid refinement of the intervention for further testing. Further development of the intervention will also enable the research team to write an intervention manual and training module.

2 RATIONALE

Currently, there are no specific interventions in the UK that focus on expanding social networks for people with psychosis. If NHS services address service users' relationships, they usually focus on

established and close relationships, mainly with the service user's partner or family. However, there are good reasons to focus a new intervention on contacts outside families: a) for many service users, particularly for those who live in social isolation, families are not available and/or the potential for contacts with family members are limited; b) when service users are still in contact with families, the relationships are often well-established with little option for further change; c) services usually have already tried family interventions, if possible, at some stage in the service user's history as they are recommended by NICE guidelines for this patient group; d) family relationships can be difficult and rather stressful for some service users; and e) the reduced social networks of patients with psychosis consist mainly of family members and what is missing are other contacts, that can be more flexibly established and shaped, and that service users can also more easily terminate if they wish to.

In consultation with 30 people from various service user groups, 29 strongly endorsed the proposal for developing an intervention to expand social networks. One participant said, "This is very relevant. I witness and experience this isolation… I miss being… part of a group".

Interventions with positive evidence from other countries require adjusting to the context of the UK and the NHS. For such interventions to be stipulated by guidelines and funded in routine care by commissioners across the NHS, they need to be standardised, well specified and manualised to facilitate replicability, and evidence-based. This study therefore seeks to refine an intervention to expand social networks in patients with psychosis so that it is feasible, acceptable, effective and cost-effective in different context across the UK, and scalable into routine practice in the NHS.

This study will involve stakeholders of different types in the refinement and adaptation of the intervention to the NHS. A qualitative approach would enable an in-depth consideration of the views of patients, carers and NHS frontline clinicians in order to specify how the intervention needs to be adapted for delivery in routine mental health services. Focus groups are normally the methodology of choice for helping experts to generate ideas as they allow participants to build on each other's views. Hence we will organise focus groups with all the three stakeholders. However, in consideration of potential logistic issues in recruiting patients to focus groups, who may be socially isolated or may not feel comfortable in a group, we will also provide options for individual qualitative interviews if some patients prefer that.

The Intervention

This study will help to devise a novel intervention to increase patients' social networks based on an intervention which showed effectiveness in a previous study in Italy (Terzian et al. 2014). A provisional description of the intervention will be presented to the participants in focus groups and interviews:

The intervention will be delivered over 6 months. In the first meeting, clinicians will discuss the patient's social network and the types of activities that they enjoy and would like to do more of. It is likely that clinicians will meet each patient once per month, and they may also arrange additional support, which might be delivered by phone, text or email. The first sessions are likely to last longer (perhaps up to 1.5 hours) with future sessions lasting 30-45 minutes. In the following sessions, clinicians will support the patient to take part in an agreed activity, which will involve meeting and communicating with others. At the end of each session, the clinician and patient will agree on an action, which will be revisited and discussed at future sessions. It's likely that the sessions will also be used to discuss good experiences and problems that patients may face when meeting others.

2.1 Assessment and management of risk

Risks of the project and measures to prevent them

We do not foresee any significant ethical, legal or management issues arising from this study.

Participation: There are unlikely to be adverse effects of taking part in the research. However, social isolation and ways to overcome it may be sensitive topics for some participants and they may find discussing the subject matter in focus groups and interviews upsetting. We will minimise this risk by:

1. Explaining the purpose of the research and basic topic guide content to participants at the recruitment stage to manage expectations.

2. Participants will not be asked to share their own personal experiences (although they are free to do so if they wish).

3. Informing participants that they may leave focus groups or interviews at any time and that they do not have to answer any questions that might make them feel distressed or uncomfortable. Individual interviews will be offered to those patients who would prefer to share their views individually with a researcher, rather than in a focus group setting.

4. Informing patients that the research team are able to contact their clinicians if they would like further support.

Confidentiality: To protect the personal data of participants, study IDs will be created and assigned for each individual, and person-identifiable data will be stored separately in a locked filing cabinet at each participating Trust. An electronic file with restricted access (to the core SCENE research team only) will be maintained at each site. Only an ID list (which will not contain any patient identifiable data) with socio-demographic and general clinical data (as per the demographic form) will be transferred via encrypted email (nhs.net) from the collaborating sites to the central study team at East London NHS Foundation Trust. A log will document any formal changes to the ID list document.

Where the researcher has concerns regarding the participant's safety or the safety of others, through participant disclosures of thoughts/plans of harming themselves or others, or through criminal disclosures; then the researcher is obliged to break confidentiality and inform the relevant clinical teams, services and/or authorities. This will be made clear to the participant on the information sheet and during the consent process to ensure their understanding.

Focus groups and interviews will be asking for participant views and opinions of the intervention. Although we do not expect participants to share personal experiences, some participants may wish to refer to personal experiences to illustrate certain views and opinions. We will emphasise that participants do not have to share personal experiences or anything that they do not feel comfortable with. We will also ensure that anonymity is preserved during data analysis.

To further protect confidentiality, we will:

- Ensure that participants understand during the informed consent process where interviews and focus groups might be audio-recorded, the purpose of this, how the audio files will be stored, and who will have access to these files (see section 9.3)
- Remind all participants that they do not have to answer any questions or make any personal disclosures if they do not wish to

- Refrain from using participants' names during audio-recorded interviews. For focus groups, we will ask participants to refer to one another using anonymous labels
- Set ground rules for focus groups to remind participants about confidentiality (i.e. we will ask them not to share information outside of the focus group) and to respect others' opinions. We expect a range of views, and we do not aim to reach alignment of opinions.

Use and storage of personal data: All participant data collected will be pseudonymised and handled in line with the Data Protection Act 1998. All audio-recorded data will be encrypted and password protected. Data will be handled and stored in accordance with the conditions set out by the study sponsor (East London NHS Foundation Trust).

The qualitative interviews and focus groups with participants will be audio recorded on an encrypted device and an NHS-approved professional transcription company will be used to transcribe the data. The company will receive the audio files over a secure, encrypted connection and all identifiable data (name of participants or any information that by itself, or in conjunction with other material, may identify a participant or other people) will be removed from the transcripts. Following transcription and completion of data analysis, the audio-recordings will be destroyed.

Benefits of the project

There is a promising emerging evidence base to support the effectiveness of interventions to increase the social networks of people living in the community with psychosis. A potential benefit for all participants taking part in this study is that their suggestions and experiences are incorporated into developing a new intervention which may be helpful to extend the social networks of service users with psychosis.

For staff, they will also be providing their expertise of working in mental health care and of barriers to implementation of new interventions. This will help the research team to find solutions and strategies to tailor the intervention to the needs of patients, carers and staff within an NHS context; and to develop an intervention that is flexible for scalability into routine NHS practice.

Safety reporting

The study will consist of a focus group or individual interview (WP2), which is in addition to patients' usual care. Adverse Events and the need for Urgent Safety Measures are not anticipated.

Adverse Events (AE)

Any adverse events will be recorded in the study file and the participant's records, if appropriate. The participants will be followed up by the research team.

Serious Adverse Event (SAE)

SAEs that are "related" and "unexpected" will be reported to sponsor within 24 hours and to the main REC within 15 days of learning of the event.

Urgent Safety Measures

In the case of urgent safety measures being required, the CI will inform the sponsor and the REC of the event immediately via telephone. The CI will then inform the REC and the JRMO in writing within 3 days.

Annual Safety Reporting

If required by the REC, the CI will send the Annual Progress Report to the main REC using the NRES template and to the sponsor.

Overview of the Safety Reporting responsibilities

The CI will ensure that safety monitoring and reporting is conducted in accordance with the sponsor's requirements.

3 STUDY DESIGN

Qualitative study including focus groups and individual interviews.

4 STUDY SETTING

This multi-centre study will is hosted by East London NHS Foundation Trust and will take place across the following NHS Trusts: East London NHS Foundation Trust; Tees, Esk & Wear Valleys NHS Foundation Trust; Devon Partnership NHS Trust.

Patient, carer and staff participants will be recruited and data collected in quiet rooms across all these Trusts, which contain the following sites: East London, Luton, Bedfordshire, North East (York, North Yorkshire, Teeside and Durham) and Devon.

Participants across all sites will be identified through secondary care mental health services.

5 ELIGIBILITY CRITERIA

5.1 Inclusion criteria

For service users:

- 18-65 years old
- Diagnosis of psychotic disorder (ICD-10 F20-29)
- Receiving secondary care mental health services
- Capacity to provide informed consent
- Ability to communicate in English

For staff:

- Mental health professional with experience of providing community mental health care.
- Aged 18-65 years old
- Employed by participating NHS Trusts
- Capacity to provide informed consent
- Ability to communicate in English

For carers:

- Over 18 years old
- Currently caring for a family member or friend who is receiving secondary care mental health services and has a diagnosis of a psychotic disorder (ICD-10 F20-29)
- Capacity to provide informed consent
- Ability to communicate in English

5.2 Exclusion criteria

For service users:

- Does not meet inclusion criteria
- Primary problem of current drug addiction
- No capacity to provide informed consent
- An inpatient on a psychiatric ward at the time of recruitment

For carers

- Does not meet inclusion criteria
- An inpatient on a psychiatric ward at the time of recruitment

For staff:

- Does not meet inclusion criteria

6 STUDY PROCEDURES

Please see Appendix 1 for schedule of procedures.

This study is part of a larger programme of research to improve social networks and quality of life in people with psychosis. It will refine an intervention for use in the NHS and develop a preliminary training module, which will be further tested in subsequent work packages. It will also help to develop information for participants to help with recruitment to a future larger trial.

Consent

Eligible patients and carers will be identified by members of the clinical team, who will introduce the study and if interest is shown request their verbal permission to pass their contact details to a member of the research team. Clinicians will provide the researchers with the names and contact details of the interested patients and carers by phone, face-to-face or secure email (encrypted NHS to NHS account). The screening and first approach will be made by a member of the wider care team (not the main treating clinician) and the consent for participation will be discussed with a researcher, who is independent from the care team. Carers may also self-refer in response to posters displayed in community locations; informed consent will be sought from eligible patients, carers and staff to participate in this study, which will include permission from patient participants to access medical records to retrieve socio-demographic and clinical characteristics. Participants will be given the option during the consent process to receive a copy of the findings from the focus groups and interviews. This will be a lay summary of results developed with the assistance of the LEAP.

The assessment of capacity will be done in two stages: in a first stage (when obtaining assent) this will be conducted by mental health clinicians who are trained and experienced in this assessment which is part of their everyday clinical practice. In a second stage (when obtaining consent), researchers will assess capacity again. The researchers will have experience in mental health studies and will be trained by experienced clinicians (Giacco and Priebe) in assessing capacity to consent to research.

Demographic and clinical characteristics data collection

The research team member conducting the focus group or interview will ask participants about demographic and clinical characteristics and record this on a form. Alternatively, participants will be given the option to complete this for themselves. Any information that patients are unable to provide will be collected from patients' medical records with their consent.

Focus groups

Focus groups will be audio-recorded using two audio recorders and facilitated by a moderator and an assistant. The moderator will first hand out a description of the intervention ("intervention description") to each participant and read it through with them. The moderator will then facilitate discussion to assess the acceptability and feasibility of the intervention within an NHS context. Participants will also be asked about possible modifications in the presentation and terminology of the trial description that would make them more or less likely to participate. These questions will be facilitated by showing participants a Trial Information Leaflet. A topic guide has been developed in discussion with SUGAR to aid the moderator in facilitating focus groups. The topic guides are broadly similar for staff, carer and patient focus groups. The assistant will take notes focusing on areas of strong agreement or disagreement and wider group dynamics. Focus groups will last between 60-90 minutes. Where participants are unable to attend a group due to unforeseen circumstances on the day, they will be offered an individual interview to facilitate participation. Focus groups will take place in quiet rooms in community mental health settings across the listed sites. Participants will be asked to attend one focus group.

Interviews

Patient interviews will be conducted to facilitate participation from patients with a high level of social isolation who might find it difficult to attend a focus group. Interviews will be audio-recorded and facilitated by a researcher, who will first give the participant a description of the intervention ("intervention description") and read this through with them; to facilitate patient views and opinions around the acceptability and feasibility of the intervention within an NHS context. Participants will also be asked about possible modifications in the presentation and terminology of the trial description that would make them more or less likely to participate. These questions will be facilitated by showing participants a Trial Information Leaflet. Interviews will last between 45-60 minutes and participants will be asked to attend one interview. Focus groups and interviews will take place in quiet rooms in community mental health settings across all sites. Individual interviews may also be carried out in patients' homes.

Discussions for both focus groups and individual interviews will cover the possible modifications in the presentation and terminology of the trial description that would make them more or less likely to participate; feasibility and acceptability of the intervention; factors that may facilitate or hinder its implementation in practice; needs to reduce, complement or amend elements of the intervention; suggestions for further specification of the extent to which the intervention should be tailored to

different sub-groups of patients and different local contexts; and the level of information on local options for activities and support for internet use that should be potentially provided as part of the intervention.

Payment to participants

Patients and carers taking part in focus groups will be offered £20 cash or voucher as reimbursement for their time after completion of the focus group. They will also be offered up to £20 cash each for any travel costs incurred.

Clinicians attending focus groups will be offered up to £20 cash for any travel costs incurred.

Patients taking part in individual interviews will be offered £20 cash or voucher as reimbursement for their time after completion of the interview.

6.1 Recruitment

Patients will be identified by clinicians and clinical studies officers (CSOs) using medical records where necessary. At this stage, the minimum amount of information will be logged to ascertain eligibility: name, RIO or NHS number, diagnosis and inpatient status. Carers will be identified by clinicians, but may also self-refer in response to posters displayed in community locations. Patients, carers and staff participants will be recruited for focus groups that will take place in months 4-6 inclusive. Recruitment for individual interviews with patients will continue for the remainder of the study (please see Appendix 1 for a Schedule of Events).

6.1.1 Participant identification

Patients will be recruited from the caseloads of secondary care mental health teams. Clinicians or CSOs, who are part of the clinical team will screen and identify eligible patients. The identified patients will be given information about the study from their clinical team (face-to-face or by phone). Patients who are interested in taking part may contact the research team directly. The research team will not contact patients or speak with them directly unless they have received permission from clinicians to do so.

Clinicians and CSOs will also identify eligible carers. Carers will be given information about the study from clinicians (face-to-face or by phone). Carers who are interested in taking part may contact the research team directly. The research team will not contact carers or speak with them directly unless they have received permission from clinicians to do so. Carers may also self-refer to the research team by responding to posters displayed in community locations.

Clinicians will provide the researchers with the names and contact details of the interested patients and carers by phone, face-to-face or secure email (encrypted NHS to NHS account).

Mental health professionals with different roles who fit the eligibility criteria will be asked to participate in focus groups. They will be approached by email, letter, phone or in person.

For individual patient interviews, patients will be offered an individual interview if they would prefer to share their views with a researcher one-to-one rather than within a focus group. Clinicians will also be approached to identify eligible patients. This purposive sampling will consider gender, age and ethnic background. There is likely to be a selection bias as to who can be recruited, but we assume that the more flexible arrangements of individual interviews as compared to focus groups and the different set-up will provide us with wider views.

6.2 Consent

Information sheets and consent forms will be written to support and record the consenting process.

All participants who respond to study information with interest will be contacted and invited to attend a face-to-face meeting. Researchers will go through information sheets with interested individuals and time taken to answer any questions or concerns that are raised. At this stage, contact details will be confirmed, and availability ascertained for attendance of focus groups and interviews.

All participants will be asked to provide informed consent, by initialling, signing and dating an informed consent form before any data collection begins. A written consent form will need to be signed by the participant and a member of the research team in order to proceed with study participation. The participant will keep one copy and the research team will keep the original which will be scanned and uploaded to the electronic medical records. During the consent process, participants will be asked if they would be happy to be contacted about other studies related to expanding social networks. Participants who agree to being contacted again will be approached for related studies at a later date. Participants' names and contact details will be kept for this purpose except where participants withdraw from the study, and this will be made clear on the information sheet and during the consent process. Participants will also be given the option during the consent process to receive findings from the study, and permission will be sought to access medical records to retrieve clinical characteristics.

Throughout this study, capacity will be checked when people are approached by the clinical team and again when informed consent is sought by the researcher. Researchers will discuss the information sheet with patients and answer any questions they might have. If there are doubts about the person's capacity to consent, this will need to be resolved before proceeding with study participation, and this will be done in discussion with patients' consultants where necessary. If doubts about an individual's capacity emerge during the recruitment process, or during their participation, their capacity to consent will be re-evaluated before continuing with study participation. The focus groups and interviews are expected to last around 60 minutes and therefore it is unlikely that people will lose capacity during this time. Researchers will have experience in mental health research and will receive training from clinically trained researchers (Giacco and Priebe) in assessing capacity to consent to research. They will use a standard template (Capacity Checklist) for assessing and documenting capacity.

If individuals decline to participate, or withdraw their participation, this decision will be respected and patients are not required to give a reason for declining or withdrawing their participation. This decision will not have any impact on the patient's treatment or rights, and this will be made clear to patients on the information sheet and by researchers during the consent process.

6.3 Study assessments

Socio-demographic and clinical characteristics will be collected from all patient participants before completion of the focus group or interview. Modified forms will be used to collect socio-demographic data from staff and carer participants. Qualitative data only will be collected through focus groups and individual interviews.

6.4 Withdrawal criteria

During the consent process, researchers will ensure that participants are aware of their right to decline participation at any stage of the research and that withdrawing participation will not affect their treatment or rights. For participants of focus groups, it will be explained that any information provided during the focus group (with the exception of the socio-demographic and personal data) cannot be eliminated from the study data as this will cause loss of information also from the other study participants. However, the quotes of those who want to withdraw will not be used in dissemination if that is their wish. Participants of individual interviews and surveys will be able to ask that their data is eliminated before the end of month 12 from the start of the project.

If a participant wishes to withdraw from the study, researchers will record date of withdrawal and reason(s) for withdrawal.

7 STATISTICS AND DATA ANALYSIS

The analysis of the data will be discussed with the LEAP, which will have been established at the start of the programme and the LEAP members will help interpretation of the findings.

The number of screened participants, eligible participants and of those who refused participation or were not approached will be recorded. Descriptive statistics will be reported for socio-demographic data.

7.1 Qualitative Data Analysis Plan

Audio recordings from focus groups and interviews will be transcribed verbatim and participant-identifiable data will be removed. A thematic analysis as described by Braun and Clarke (2006) will be conducted using NVivo qualitative analysis software (the most widely used programme to aid with qualitative analysis), and following the stages of data reduction, data display and conclusion drawing/ verification as described by Miles and Huberman (1994).

Two researchers will conduct the thematic analysis to identify themes emerging in the transcripts. This will involve one researcher analysing the transcripts for themes that reflect the content of the text. Related themes will be clustered together. This process will be repeated several times, and a second researcher will contribute to the analysis by reading the transcripts and ensuring that no theme is over or under-represented. Any disagreements will be discussed iteratively until a decision is reached. Eventually, each group of themes will be given a label, which reflects its content. Each group label will be referred to as a Main Theme and the components will be referred to as Sub Themes.

Based on the results of focus groups and interviews, which will be further discussed in the project team, with the LEAP and with the Programme Management Group, the initial ideas about the intervention and training will be further developed. This process will lead to a more detailed preliminary manual for the intervention and a preliminary training module.

7.2 Sample size calculation

Three focus groups will consist of mental health professionals from different backgrounds, three focus groups will consist of carers, and three further groups will consist of patients. An additional nine

patients will be invited to participate in individual interviews. This will provide an overall sample size and number of focus groups which is higher than the average in healthcare studies (Ritchie, Lewis and colleagues (2014) and make us confident we can reach saturation and obtain helpful information from all the sites.

Finch, Lewis & Turley (2013) suggest an optimum group size of 6-8 participants per focus group. This will enable active participation of all members whilst allowing for more detailed discussions from individual members.

There is a possibility that some participants will not be able to commit to attending focus groups on the day, for example, due to problems related to their mental health condition or urgent work-related issues. Therefore, individual interviews will be offered to those who do not attend on the day to increase access to participation.

Separate groups for patients and staff will be conducted due to the sensitive nature of the topic and the likely divergent views amongst participant groups, which may inhibit an open discussion and therefore not be the best use of participants' and the research team's time. Likewise, to avoid group dynamics being affected by perceived staff hierarchies and to tailor the topic guide usefully, separate groups will be held for senior managers and junior staff.

There will therefore be a maximum of 24 and a minimum of 18 staff participants, a maximum of 24 and a minimum of 18 carer participants, and a maximum or 24 and minimum of 18 service user participants. A further 9 patients will be recruited for the individual interviews, sampled purposively with the aid of clinicians.

7.3 Subject population

All patient data collected will be subject to data analysis as described in this section. The exception is where participants withdraw from surveys or individual interviews. In these instances, data will be deleted if this is requested before the end of month 12 from the start of the project. It will otherwise be included in the analysis. This will be made clear to all participants during the consent process and on the information sheet.

Because withdrawal of data from focus groups would lead to loss of data from other participants, it will be explained to participants during the consent process and on the information sheet that all data collected during focus groups cannot be withdrawn. However, if participants of focus groups wish to withdraw from the study, then socio-demographic and personal data will be deleted. In addition, their quotes will not be used in subsequent publications or presentations if that is their wish.

8 MONITORING, AUDIT & INSPECTION

The study will be monitored and audited by the sponsor of the study, East London NHS Foundation Trust in accordance with SOPs approved by NOCLOR.

A Programme set-up meeting with the PCTU Team has been held prior to commencement of data collection. A multidisciplinary risk assessment will be conducted including the PCTU QA manager, CI and other relevant staff members. Based on the risk assessment, an appropriate study monitoring and auditing plan will be produced according to PCTU SOPs. This monitoring plan will be authorised by the CI/Sponsor before implementation. Any changes to the monitoring plan will be agreed by the

CI/Sponsor. Monitoring visits and procedures will be recorded in the TMF and will adhere to the SOPs of both NOCLOR and the PCTU.

9 ETHICAL AND REGULATORY CONSIDERATIONS

9.1 Research Ethics Committee (REC) review and reports

"The Principal Investigator will ensure that the study will be carried out in accordance with the ethical principles in the Research Governance Framework for Health and Social Care, Second Edition, 2005 and its subsequent amendments as applicable and applicable legal and regulatory requirements".

As this study will be lead from England and involves NHS service users, before the study starts it will require approval from the Health Research Authority (HRA) and REC Favourable Opinion for the study protocol, informed consent forms and other relevant documents, e.g. information sheets.

Any substantial amendments requiring review by the REC will not be implemented until a favourable opinion has been granted and approved by the relevant NHS R&D departments and HRA.

The Chief Investigator will notify the REC, HRA and study sponsor of the end of the study, and will immediately notify the REC, HRA and study sponsor should the study end prematurely. This will include notification of the reasons for premature termination.

Capacity:

The assessment of capacity will be done in two stages: in a first stage (when obtaining expression of interest and permission to contact individuals), capacity will be assessed by trained and experienced mental health clinicians. In a second stage (when obtaining informed consent), researchers will assess capacity again. The researchers will have experience in mental health studies and will be trained by experienced clinicians (Giacco and Priebe) in assessing capacity to consent to research. They will use a standardised template (Capacity Checklist) for assessing capacity.

Informed consent:

As detailed in section 6.2, the study researchers will explain to participants what will be expected of them and how long they would be in the study for. The researchers would also ensure they are aware of their right to decline participation at any stage of the research and clarify that declining to participate will not result in any consequences whatsoever on patient treatment. All participants will receive a written information sheet. All participants will be given the option to have the contents of the sheet read aloud to them by the researchers. Researchers will answer all participants' questions about the study before proceeding with the study, and they will have time to decide whether they wish to participate. A written consent form will need to be signed by the participant and a member of the research team in order to proceed with study participation (one copy will be given to the patient). The study team will retain the originals and scan and upload a copy to patent electronic medical records. In the rare case that electronic medical records will not be available or not functioning, we will file a paper copy in paper-based medical records.

Data collection:

Experienced and trained researchers will conduct the surveys, focus groups and individual interviews. If a participant shows signs of irritation or dissatisfaction, or any other untoward psychological reaction, the session can be stopped immediately, and researchers will contact the treating clinicians.

Participants will be made aware that they are not expected to make personal disclosures and that they do not have to answer any questions that might make them feel uncomfortable or distressed.

Data protection:

Data will be pseudonymised and securely stored. The patients will be identified in datasets and information sheets only by a personal identification number. Patient-identifiable data will be stored securely and accessible only by the research team.

9.2 Public and Patient Involvement

Patient and public involvement has already been sought to further develop initial ideas for this study and the related programme of research through:

- SUGAR (Service Use and Carer Advisory Group on Research) at City University London
- Patient Engagement Group at East London NHS Foundation Trust
- A Community Health Network lay advisors meeting arranged by the McPin Foundation
- A peer review panel at the McPin Foundation

A Lived Experience Advisory Panel (LEAP) will be set up and it will meet every four months throughout the study to advise on the research itself, review material and support the overall public and patient involvement. The LEAP will be chaired by a service user who is also a co-applicant on this programme of research, and who will also recruit members from SUGAR and the associated network of users with research interest and experience.

The LEAP will have a central role in the preparation of study material, design of practical procedures, and dissemination. For the development of open questions that form part of the survey in WP1, we will work with SUGAR to develop this as the LEAP will not yet be formed. The LEAP will then help with the development of topic guides for the focus groups and interviews that form WP2 and 3. The LEAP chair will attend regular meetings with the project team and she will be directly involved in parts of the research, in particular the interpretation of qualitative material from interviews and focus groups. Findings from all work packages, and ways to further develop the intervention and training will also be discussed with the LEAP. The LEAP's role in dissemination is further described in Section 10.

9.3 Data protection and patient confidentiality

All researchers and study staff must comply with the requirements of the Data Protection Act 1998 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

Personal information:

All participants will be assigned a participant ID number and this will be used for all data processing purposes. Participants' names and contact details will be retained (with their permission) to re-approach them to take part in related studies and to share research findings. As the project linked to this is funded for five years, it is envisaged that participants might want to know how their information and suggestions have helped to shape the service on offer.

Directly identifiable patient data (participants' names, contact details, socio-demographic data) and the list linking these data with participant ID number will be password-protected and stored on secure servers at participating research sites', which will only be accessible by the research programme (SCENE) team members on a need-to-know basis. All hard copies of data including socio-demographic forms, consent forms, service user receipts will be kept in lockable filing cabinets on NHS premises of participating sites, and only accessible to the research team members on a need-to-know basis.

Audio recordings:

The focus groups and interviews will be audio-recorded with participants' permission. Audio recordings will be stored on secure servers in participating Trusts, with access restricted to appropriate members of the research team. Audio recordings from participating sites will be transferred to the host site using encrypted USB sticks and then transcribed using a NHS-approved professional transcription company. The audio recordings will be destroyed immediately after transcription and analysis. Once transcribed, all identifiable information will be omitted or replaced with pseudonymised labels.

Record retention and archiving

In accordance with the Research Governance Framework and East London NHS Foundation Trust Record Management and IM&T Information and security policies, research data will be archived as per East London NHS Foundation Trust procedures and kept for 20 years in the Trust Modern Records Centre. Identifiable data will be kept only for study duration and then destroyed. The exception to this would be where participants have given consent for us to contact them about future related studies.

The Chief Investigator will be data custodian.

9.4 Indemnity

The study will have indemnity through a standard NHS insurance scheme. NHS indemnity does not offer no-fault compensation i.e. for non-negligent harm, and NHS bodies are unable to agree in advance to pay compensation for non-negligent harm. They are able to consider an ex-gratia payment in the case of a claim.

9.5 Amendments

If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor must submit a valid notice of amendment to the REC for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice. It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of the submission to the REC.

The amendment history will be tracked via version and date control of protocols, with changes to the protocol highlighted in the Appendix 2.

10 DISSEMINATION POLICY

10.1 Dissemination policy

Dissemination activities will be influenced and supported by the LEAP. Throughout all phases of the research, we will disseminate information about the activities of the programme through social media and a project specific website in order to reach a wider public audience. The website will have sections for patients, professionals and service commissioners; and will be linked to other websites of local authorities, the participating NHS Trusts, *and the academic institutions of the applicants.*

When results of the different work packages become available, they will be disseminated using the same Channels, as well as through:

- scientific publications in peer-reviewed open access journals;
- presentations at national and international conferences and to professional and non-professional audiences at appropriate events;
- existing networks, in particular
  a) the WHO, utilising the status of the Unit for Social and Community Psychiatry at QMUL as a WHO Collaborating Centre,
  b) the NHS, e.g. the benchmarking network in mental health which is currently co-ordinated by East London NHS Foundation Trust;
  c) the organisation involved in specific Quality Improvement programmes in health care
  d) different professional networks of the applicants;
- workshops and presentations at meetings that are held either as regular events (e.g. East London Mental Health Research Presentation Day, Showcase Conferences of CLRN) or specifically organised at different NHS locations;
- responding to invitations for presentations in different organisations; our experience with developing a new intervention in a PGfAR in the NHS, i.e. the DIALOG+ intervention, has shown that the news of an effective new intervention can spread quickly and lead to many invitations to present; we will arrange that all members of the project team including Research Assistants are in a position to give such presentations and prepare a regularly updated 'road show' for this.

Workshops for NHS Trusts and service user organisations will be delivered in collaboration with the LEAP. The LEAP will also be actively involved in developing lay summaries of the findings.
Study findings for each work package will be sent to participants who gave their permission during the informed consent process. The report will not include any identifiable information. The timeline for the reports will be explained to participants by the researcher during the consent process.

Foreground intellectual property (IP) will be developed during the course of the programme including (but not limited to) a manual for carrying out structured interviews and an associated training programme (and web-based training module, which will be embedded within the project-specific website).
IP protection: All discussions concerning the development of the manual and training programmes will be kept confidential among the research team before the IP is published.

The funders (NIHR) will be contacted at least 30 days prior to any publication arising from the project. Within the publications, the funding body will be acknowledged using the standard text as set out within the research contract.

10.2 Authorship eligibility guidelines and any intended use of professional writers

Authorship will be determined by contribution to the study design, data collection, data analysis and writing up of the study. No professional writers will be used to write study reports.

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12 APPENDICES

12.1 Appendix 1– Schedule of Procedures

		Month											
	Procedures		**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
	Eligibility screening													
	Initial meeting to discuss study													
	Informed consent													
	Socio-demographics													
	Patient focus groups													
	Carer focus groups													
	Staff focus groups													
WP2	Patient individual interviews													

12.2 Appendix 2 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made